

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Prakash Subbiah on 06/15/2011.

The application has been amended as follows:

In the claims:

Claims 1-30 are cancelled.

31. A method for identifying cardiac transplant tissue rejection in a human subject, said method comprising:

determining a first gene expression profile in a blood sample taken from said human subject, wherein said first gene expression profile comprises the nucleic acid expression level of the ubiquinol-cytochrome c reductase binding protein (UQCRB) gene; and

comparing said first gene expression profile to a second gene expression profile, wherein said second gene expression profile comprises the nucleic acid expression level of the UQCRB gene derived from blood samples collected from a human cardiac transplant population that does not have cardiac transplant tissue rejection,

wherein a statistically significant increase in UQCRB gene expression in said first gene expression profile compared to said second gene expression profile is indicative of cardiac transplant tissue rejection in said human subject.

32. The method of claim 31, wherein said first and second gene expression profiles further comprise the nucleic acid expression level of the basic transcription factor 3 (BTF3) gene, the suppression of tumorigenicity 13 (ST13) gene, and the cullin 4A (CUL4A) gene.

33. The method of claim 32, wherein a statistically significant increase in BTF3, ST13, or CUL4 gene expression in said first gene expression profile compared to said second gene expression profile is indicative of cardiac transplant tissue rejection in said human subject.

34. The method of claim 31, wherein said first and second gene expression profiles further comprise the nucleic acid expression level of the CASP8 and FADD- like apoptosis regulator (CFLAR) gene.

35. The method of claim 34, wherein a statistically significant decrease in CFLAR gene expression in said first gene expression profile compared to said second gene expression profile is indicative of cardiac transplant tissue rejection in said human subject.

36. The method of claim 31, wherein said first and second gene expression profiles comprise the nucleic acid expression level of a plurality of expressed sequence tags (ESTs).

37. The method of claim 36, wherein at least one of said expressed sequence tags comprises a nucleic acid comprising SEQ ID NO: 12.

38. The method of claim 31, wherein the identified cardiac transplant tissue rejection is a cardiac allograft.

39. The method of claim 31, wherein said determining a first gene expression profile is conducted by the use of a microarray.

2. The following is an examiner's statement of reasons for allowance:

In light of the Applicants amendments to the claims and Remarks of 06/28/2010, and the Examiners Amendments as detailed above, the claim objection set forth on pages 3-4 of the Office Action of 12/28/2009, and the claims rejections under 35 USC 112 2nd paragraph and first paragraph, as set forth on pages 4-9, are **WITHDRAWN**. The prior art does not teach or suggest a method of identifying cardiac transplant tissue rejection wherein UQCRB expression is determined in a blood sample taken from an individual, and the increased expression of UQCRB mRNA in the blood sample is indicative of the rejection, as is taught by the disclosure of the instant application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN KAPUSHOC whose telephone number is (571)272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634